K110809

JUL - 5 2011

510(k) SUMMARY

A Summary of 510(k) Safety and Effectiveness Information in Accordance with the Requirements of 21 CFR 807.92.

Submitter Information	
Name	Frank Pokrop
Address	CareFusion Inc., 3750 Torrey View Court. San Diego, Ca 92130
Phone number	Work - (858) 617-4364. Cell: (858) 245-8197
Fax number	(858) 617-6735
Establishment Registration Number	2016493
Name of contact person	Frank Pokrop
Date prepared	March 15, 2011
Name of device	
Trade or proprietary name	Trade name is still being determined
Common or usual name	Wireless Monitoring System
Classification name	Cardiovascular Monitoring Devices
Classification panel	Cardiovascular
Regulation	21 CFR Part 870.2910
Product Code(s)	DRG
Legally marketed device(s) to which equivalence is claimed	(1) Philips Intellivue Patient Monitor. 510(k) #: K052961 (2) Nihon Koden Multiple Patient Receiver. 510(k) #: K071058,
Reason for 510(k) submission	New device.
Device description	The proposed device consists of a patient patch with integrated temperature sensor, an electronic bridge and server software. The patch is attached to the patient and connected to existing monitoring leads to capture heart rate, respiration and body temperature. This data is wirelessly transmitted to a bridge. Multiple bridges can be installed in a hospital setting to capture signals in case the patient is moved or becomes ambulatory. Data from the patch is transmitted through a hard-wire connection to the nurses' station for surveillance. The healthcare practitioner can set limits on the patient data which in turn may trigger an alert.

Intended use of the device	General surveillance of non-critical acre patients who are at least 18 years of age.
Indications for use	The Wireless Monitoring System is intended for use by health care professionals for routine surveillance of patient physiological parameters to include, pulse rate, respiratory rate and axillary temperature, in a hospital setting. Data is transmitted wirelessly to a central location. Notifications can be prospectively set to notify healthcare professionals to excursions outside of selected parameters. The device is not intended to be used on critical care patients and is intended to supplement vital signs monitoring by healthcare professionals, not to replace current standards of care. The device is intended for use on general care patients and on patients who are 18 years of age or older.

Summary of the technological characteristics of the device compared to the predicate device

Characteristic	New Device	Predicate [Device Name] [510(k) number]
Central monitoring of remotely transmitted patient data	Yes	Philips Intellivue Patient Monitor. K052961 Nihon Koden Multiple Patient Monitor. K071058
Uses existing sources of physiological data	Yes	Philips Intellivue Patient Monitor. K052961 Nihon Koden Multiple Patient Monitor. K071058
Programmable alert settings and limits	Yes	Philips Intellivue Patient Monitor. K052961 Nihon Koden Multiple Patient Monitor. K071058
Data sent to central server	Yes	Philips Intellivue Patient Monitor. K052961 Nihon Koden Multiple Patient Monitor. K071058
Monitors heart rate	Yes	Philips Intellivue Patient Monitor. K052961 Nihon Koden Multiple Patient Monitor. K071058
Monitors respiration	Yes	Philips Intellivue Patient Monitor. K052961 Nihon Koden Multiple Patient Monitor. K071058
Monitors body or axillary temperature	Yes	Philips Intellivue Patient Monitor. K052961 Nihon Koden Multiple Patient Monitor. K071058
Can be used with a general hospital patient population	Yes	Philips Intellivue Patient Monitor. K052961 Nihon Koden Multiple Patient Monitor. K071058
Monitors multiple patients	Yes	Philips Intellivue Patient Monitor. K052961 Nihon Koden Multiple Patient Monitor. K071058

Uses both AC Main and battery power	Yes	Philips Intellivue Patient Monitor. K052961 Nihon Koden Multiple Patient Monitor. K071058

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE*

Performance Test Summary-New Device

Characteristic	Standard/Test/FDA Guidance	Results Summary
1. Packaging - biocompatibility	ASTM 2475-05	The proposed device passes the applicable tests and standards.
2. Basic safety	IEC 60601-1	
3. EMC Compatiblity	IEC60601-1-2	
4. Collateral Safety	IEC 60601-1-1	
5. Electrocardiographic equipment	IEC 60601-2-27	
6. Patient Monitoring	IEC 60601-2-49	
7. Degrees of Protection	IEC 60529 IP 64	
8. Human exposure to electromagnetic fields	IEC 62311	
9. IT Equipment	IEC 60950-1	
10. Animal welfare	ISO 10993-2	
11. Interactions with Blood	ISO 10993-4	
12. In Vitro Cytotoxicity	ISO 10993-5	
13. Irritation and Skin Sensitization	ISO 10993-10	
14. Systemic Toxicity	ISO 10993-11	
15. Sample Preparation	ISO 10993-12	
16. Leachable Substances	ISO 10993-17	
17. Chemical Characterization of Materials	ISO 10993-18	
18. Risk Management	ISO 14971	

Comparative Performance Information Summary

Characteristic	Requirement	New Device	Predicate Device
FCC Approval	Letter of approval	Yes	Yes
Frequency Range	911.38-918.59 (Mhz). FCC Part 15	Same or similar	Same or similar
Type of Device	Near-patient data collection	Disposable	Non-disposable
Heart Rate	30 to 200 bpm	Same or similar	Same or similar
Axillary temp	89.6^0 F – 111.2^{0}F	Same or similar	Same or similar
Respiratory rate	5 – 60 resp/min	Same or similar	Same or similar
HL7 Protocol	Communicate with HIS using HL7	Yes	Yes

Interval reporting	Data reporting can be programmed	Range: 2-30 minute increments in 2 minute increments	Same or similar
Battery power	Low power battery for near patient device	3.0 volts	Same or similar
Power for bridges	Bridges use AC Main for power	yes	Same or similar
Notifications	System has programmable notifications	Yes	Yes
Telemetry	Transmissions between bridge and patch shall use ISM bands	Yes	Same or similar
Vital signs data	Provides: (1) heart rate, (2) Respiration rate, (3) Axillary temperature	Yes	- Same or similar - Predicate devices have these capabilities and more
Operating Paradigm	Uses: (1) Patient data collection device, (2) bridges, (3) Hospital servers	Yes	Same or similar

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION

Clinical Performance Data/Information

(1) Clinical testing was not performed with this device.

(2) Usability testing at a user site.

The University of Texas at Arlington showed that the proof of concept and the proof of operating principles were both found to be valid, the system operated and functioned as planned, staff opinions were positive with participants showing an interest in using the proposed device.

a. "The study execution went smoothly and it afforded the opportunity to conduct a realistic and rather rigorous test of system usability.

b. Based on the collective data analysis the system is considered to have good usability."

(3) Performance testing a user site.

Wireless testing at Palomar Pomerado Hospital showed that the device's wireless features operated as designed and as intended. Testing for EMI and other parameters were monitored and recorded. Attached reports show safe and effective levels of operation without harming the patient along with acceptable levels of performance. From the report:

a. "The System Patch and Bridge did not interfere with any wireless equipment provided by the hospital for the testing.

b. Further no in hospital equipment noise or interference had any impact on the operation of the System."

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

The device was found to be safe and effective and it operated as intended in user environments.

*Although a table format is shown and recommended, use whatever format is appropriate for your medical device or *in vitro* diagnostic product.

** Insert as many lines as necessary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL - 5 2011

CareFusion, Inc.
c/o Mr. Frank Pokrop
Director, Regulatory Affairs
3750 Torrey View Court
San Diego, CA 92130

Re: K110809
Trade/Device Name: Wireless Monitoring System
Regulatory Number: 21 CFR 870.2910
Regulation Name: Radiofrequency physiological signal transmitter and receiver
Regulatory Class: II (two)
Product Code: DRG
Dated: June 3, 2011
Received: June 6, 2011

Dear Mr. Pokrop:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110809

Device Name: Wireless Monitoring System

The Wireless Monitoring System is intended for use by health care professionals for routine surveillance of patient physiological parameters to include, pulse rate, respiratory rate and axillary temperature, in a hospital setting. Data is transmitted wirelessly to a central location. Notifications can be prospectively set to notify healthcare professionals to excursions outside of selected parameters.

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Prescription Use _ **XXX**_
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter use____
(21 CFR Part 801 Subpart C)

(PLEASE DO NO WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

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